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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,809	07/30/2001	Robert David Possee	46309-257438	7430

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,809

Applicant(s)

POSSEE ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-34 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 27-34 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 4/23/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 5/17/05. Claims 1-26 and 35-50 have been cancelled. Claims 27-34 are pending in this application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein and therefore, this action is final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campos et al (US 6,911,206; see entire document) in view of Lee et al (US 5,348,886; see entire document).

This rejection is maintained for reasons of record in the office action mailed 1/13/06 and restated below.

Applicants claim a method of cloning a gene comprising the steps of providing a naked circular replication-deficient baculovirus vector and a “rescue” vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking in the baculovirus vector such as *lef-2*. The vector is furthermore capable of being maintained in bacteria.

Campos et al teach a method for cloning a fusion gene encoding a BHV-1 antigen and lutenizing hormone (gD:LH). The method involves providing a naked replication-deficient baculovirus vector and providing a transfer vector that comprises genes that complement for replication deficiency, or a rescue vector (see col 33, line 35- col 34, line 36). Campos et al do not teach any processes of linearization or digestion of the vector and therefore, absent evidence to the contrary, the vector is circular. The vectors are co-transfected into Sf21 insect cells as recited in part in claims 27 and 28.

Campos et al do not teach the use of a replication deficient baculovirus vector that is capable of being maintained in yeast or bacteria cells. Campos et al do not teach the specific gene that is deficient to render the baculovirus replication deficient.

Lee et al teach that baculovirus can be maintained in bacterial cells by insertion of a bacterial replicon and a selectable drug-resistance marker. This vector has the expected benefit that it can replicate in *E. coli* as a plasmid and is stably inherited and structurally stable after many generations of growth (see e.g. abstract).

Merrington et al teach that *lef-2* is a gene that encodes a gene necessary for viral replication (see e.g. page 338, col 2, paragraph 2). Merrington et al teach that the *lef-2* mutation can be “rescued” by co-transfection of unmodified *lef-2*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the replication defective baculovirus vector taught by Campos et al with the bacterial replicon and selectable marker as taught by Lee et al and by inactivation of the *lef-2* gene as taught by Merrington et al because Campos et al teach that it is within the ordinary skill of the art to express replication defective baculovirus in a cell and because Lee teach that it is

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within the ordinary skill of the art to use bacteria as host cells for recombinant baculovirus vectors and because Merrington teaches that mutation of *lef-2* affects DNA replication. One would have been motivated to do so in order to receive the expected benefit of expected benefit that it can replicate in *E. coli* as a plasmid and is stably inherited and structurally stable after many generations of growth (see abstract, Lee et al) and the expected benefit that Merrington et al have defined a gene involved in DNA replication and have demonstrated that a mutation in this gene can be rescued. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 103 on pages 5-9 and in exhibit A of the amendment filed 5/17/06. Applicants argue that Campos does not disclose a circular naked replication-deficient baculovirus vector. It is applicants' contention that BacPak used in all of the examples in Campos is provided linearized as evidenced by Clontech (material provided with applicants' arguments). To this end, applicants sum the unexpected advantages of this system over BacPak.

Applicants' arguments filed 5/16/06 have been fully considered but they are not persuasive. Campos et al teach a method of cloning BHV-1 antigen and lutenizing hormone into baculovirus in which replication deficient baculovirus viral DNA and a rescue vector that is produced from BacPak. Campos et al do not teach that the replication deficient baculovirus viral DNA (hence naked) is BacPak or that the baculovirus other than occurrence of BacPak

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recombination arms is obtained from BacPak. Rather, the vector appears to be baculovirus DNA for which there is no evidence that it has been digested. This is supported by disclosure that the vector is created by steps that include identification of the digestions made in the vector in its' creation, which suggests that if the baculovirus vector were digested for use in the methods, such a step would be included.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

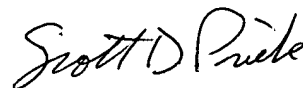
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
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A handwritten signature in black ink, reading "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER